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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,412	07/23/2004	Takashi Yasukochi	KUZ-0018	3951

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Jane Massey Licata
Licata & Tyrrell
66 East Main Street
Marlton, NJ 08053

EXAMINER	
CHEUNG, WILLIAM K	
ART UNIT	PAPER NUMBER
1796	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,412	YASUKOCHI ET AL.	
	Examiner	Art Unit	
	WILLIAM K. CHEUNG	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7,10-12,16-18,21-23 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7,10-12,16-18,21-23 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges the amendment filed December 18, 2008. Claims 1-4, 6, 8, 9, 13-15, 19, 20, 24-26 have been cancelled. Claims 5, 7, 10-12, 16-18, 21-23, 27-33 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 5, 7, 10-12, 16-18, 21-23, 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (WO 99/02141) in view of Matsumoto et al. (US 5,532,373), for the reasons adequately set forth from paragraph 4 of the office action of September 18, 2008.

Claim 27 (previously presented): A process for the production of a medical patch, said process comprising:

(a) dissolving in a lower alcohol:

(i) one or more drugs; and

(ii) an acrylic copolymer or a methacrylic copolymer comprising one or more crosslinkable acrylic or methacrylic monomer units having at least one hydroxyl group and/or carboxyl group and one or more other monomer units containing at least 2-ethylhexyl acrylate and/or vinylpyrrolidone;

(b) adding to the solution of step (a) one or more crosslinking agents selected from the group consisting of metal alcoholates, boric acid, borate and borate ester;

(c) spreading the mixture of step (b) on a film; and

(d) thermally crosslinking the polymer of (ii) with the one or more crosslinking agents of step (b) either simultaneously with or followed by laminating to a support, collectively thereby to form the medical patch.

Claim 28 (currently amended): A process for the production of a medical patch, said process comprising:

(a) dissolving in a ~~lower alcohol~~ solvent:

(i) one or more drugs; and

(ii) ~~one or more crosslinking agents selected from the group consisting of metal alcoholates, boric acid,~~

~~borate and borate ester~~ an acrylic copolymer or a methacrylic copolymer having one or more crosslinkable acrylic or methacrylic monomer units having at least one hydroxyl group and/or carboxyl group and one or more other monomer units containing at least 2-ethylhexyl acrylate and/or vinylpyrrolidone;

(b) adding to the solution of step (a) ~~an acrylic copolymer or a methacrylic copolymer having one or more crosslinkable acrylic or methacrylic monomer units having at least one hydroxyl group and/or carboxyl group and one or more other monomer units containing at least 2-ethylhexyl acrylate and/or vinylpyrrolidone to the solution~~ one or more crosslinking agents selected from the group consisting of metal alcoholates, boric acid, borate and borate ester dissolved in a lower alcohol;

(c) spreading the mixture of step (b) on a film; and

(d) thermally crosslinking the polymer of step (b) with the one or more crosslinking agents of (ii) either simultaneously with or followed by laminating to a support, collectively thereby to form the medical patch.

Kamiyama (abstract) discloses a process for preparing transdermal patches comprising an adhesive. Kamiyama (page 5, line 20-28) discloses that the preparation of the adhesive compositions mixing acrylic based materials and polar monomers such as hydroxyethyl acrylate (typically is referred as 2-hydroxyethylacrylate) and hydroxypropyl acrylate (typically is referred as 3-hydroxypropyl acrylate), and vinyl pyrrolidone to enhance drug solubility of drugs (page 2, line 3; page 6, line 1-6; page 27, claims 11, 16), such as oestradiol and norethisterone (page 13, line 3-4). Kamiyama clearly teach the use of 2-ethylhexyl acrylate (page 5, line 24) and vinyl pyrrolidone (page 6, line 4-5).

Regarding the claimed "spreading the mixture on a film", Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed drying step also indicates that the prepared adhesive film product is substantially free of water, thereby meeting the "substantially no water" feature of claim 32. Further, the mixing step teachings of Kamiyama also encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27 and 28.

Regarding the new claim 29, Kamiyama (page 2, line 3; page 27, claims 11, 16) clearly teach a process comprising the use of N-vinyl pyrrolidone (or vinyl pyrrolidone).

The difference between the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33 and Kamiyama is that Kamiyama employs peroxide as curing agent, while the claimed invention involves the use of boric acid.

Matsumoto et al. (col. 1, line 12-33) disclose a process for preparing a photopolymerizable composition for producing lithographic sheets or films, resin reliefs, resists or photomasks or printed circuit board manufacture, black and white or color transfer development sheets of development sheets. Matsumoto et al. (col. 29, 23-38) clearly disclose that the adhesive having a film backing is capable of releasing its content (a dye or a drug). Further, Matsumoto et al. (col. 27, line 65-67) disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). Matsumoto (col. 38, line 11-12) clearly teach using the claimed alcohols such as methanol, ethanol, n-propanol, n-butanol, as coating solvents. Motivated by the expectation of success of developing the

coating (adhesive) as described in Matsumoto or Kamiyama, it would have been obvious to one of ordinary skill in art to incorporate the lower alcohols teachings of Matsumoto into the Kamiyama to obtain the lower alcohol feature as claimed. In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would also have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al., or to incorporate the boric acid curing to Kamiyama additionally to the peroxide curing system of Kamiyama to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33.

Regarding the claimed "the patch has the pressure-sensitive adhesive power of from 102 gF to 267 gF after storage at 65 °C for 48 hours, in view of the substantially identical type of hydrophilic or polar type monomers (which primarily provide adhesive properties between the adhesive and the substrates) employed in Kamiyama/Matsumoto and as claimed, the examiner has a reasonable basis to believe that the claimed “pressure-sensitive adhesive power” is inherently possessed in the composition as taught in Kamiyama and Matsumoto, in the combined teachings or each individually. Since the PTO does not have proper means to conduct experiments, the

burden of proof is now shifted to applicants to show otherwise. In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

Response to Arguments

4. Applicant's arguments in the arguments and in the Declaration filed December 18, 2008 have been fully considered but they are not persuasive.

Applicants argue that the presently claimed invention uses a completely different methodology in which boric acid or metal alcoholate is dissolved in a lower alcohol prior to adding to a polymer mixture. Applicants also argue that Matsumoto et al. and Kamiyama are drawn to using different crosslinking systems. However, applicants must recognize that Matsumoto et al. (col. 27, line 65-67) clearly disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). Motivated by the expectation of success of developing the coating (adhesive) as described in Matsumoto or Kamiyama, it would have been obvious to one of ordinary skill in art to incorporate the lower alcohols teachings of Matsumoto into the Kamiyama to obtain the lower alcohol feature as claimed. In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 ^{o}C for 2 minutes, and at about 50 ^{o}C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of

Kamiyama, it would also have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al., or to incorporate the boric acid curing to Kamiyama additionally to the peroxide curing system of Kamiyama to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33.

Regarding applicants' argument that Kamiyama fails to teach or suggest any method to suppress the crosslinkage, the argument is not supported by the claims as written.

Regarding claim 27, 31, 32, applicants argue that Kamiyama fails to teach dissolution of a drug and a polymer in a lower alcohol solution before adding a crosslinking agent, applicants must recognize that Matsumoto (col. 38, line 11-12) clearly teach using the claimed alcohols such as methanol, ethanol, n-propanol, n-butanol, as coating solvents. Motivated by the expectation of success of developing the coating (adhesive) as described in Matsumoto or Kamiyama, it would have been obvious to one of ordinary skill in art to incorporate the lower alcohols teachings of Matsumoto into the Kamiyama to obtain the lower alcohol feature as claimed.

Regarding the declaration filed December 18, 2008, applicants argue that it is unexpected that only methanol (or a lower alcohol) works when running comparative reactions side by side using THF and ethyl acetate as alternative solvents. However, applicants fail to recognize that the argued "unexpected results" is not commensurate to the scope of the invention being claimed and taught in Kamiyama. Applicants must recognize that the difference between the invention of claims 5, 7, 10-12, 16-18, 21-23,

27-33 and Kamiyama is that Kamiyama employs peroxide as curing agent, while the claimed invention involves the use of boric acid, not different solvents. Therefore, applicants' declaration fails to show the criticality of the claimed invention.

In view of the reasons set forth above, the rejection set forth is proper.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/William K Cheung/
Primary Examiner, Art Unit 1796

William K. Cheung, Ph. D.
Primary Examiner
March 17, 2009